Exhibit 199
(Filed Under Seal)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK Plaintiff, v. ACTAVIS PLC, and FOREST LABORATORIES, LLC, Defendants.	Case No.: 14-cv-7473 FILED UNDER SEAL

DECLARATION OF MARCO TAGLIETTI, M.D.

I, Marco Taglietti, hereby declare as follows:

1. I am the former Executive Vice President of Drug Development & Research and Chief Medical Officer of Forest Laboratories, Inc., and former President of Forest Research Institute, Inc. Earlier I also held other positions at Forest relating to clinical and medical affairs.

Summary of Testimony

2. The key points of my testimony can be summarized as follows:

- Forest competes in the pharmaceutical marketplace through extensive investment in R&D and the development of new treatments. Product innovation is critical to Forest's success.
- NAMENDA XR® has clear benefits over NAMENDA® IR tablets, including once daily dosing, applesauce dosing, and furthering the development of a new product that combines NAMENDA XR® with another widely prescribed Alzheimer's treatment.
- Forest conducted clinical studies to demonstrate the safety and tolerability of NAMENDA XR®, including a study of patients switched from NAMENDA® IR tablets to NAMENDA XR®.
- Forest's investment of nearly [redacted] in support of NAMENDA XR® pediatric autism studies generated valuable knowledge on Autism in children through a network of clinical trial centers that can continue to be used to further the development of new treatments.
- Forest has confirmed that it will continue to sell its NAMENDA® IR oral solution.

DX303

Background

3. At Forest Research Institute, I oversaw the continued development of NAMENDA® after it reached the marketplace, the development of NAMENDA XR®, and Forest's research of other novel, innovative therapies in general. I have nearly 30 years of experience in the pharmaceutical industry. Prior to joining Forest, I served as the European Team Leader for Anti-Infectives at the Marion Merrell Dow Research Institute, Vice President of Clinical Development at Schering-Plough, and Senior Vice President of R&D at Stiefel Laboratories.

4. I am a physician. I have board certifications in dermatology and infectious diseases from the Università degli Studi di Pavia, where I attended medical school.

Research and Innovation Are Critical to Forest

5. As a branded pharmaceutical company, Forest competes primarily through innovation. To survive as a business, Forest must continue to develop new therapies that offer benefits to patients, their caregivers and physicians.

6. To that end, Forest spends hundreds of millions of dollars each year on research and development. In between 2010 and 2014, Forest's annual R&D budget ranged from approximately [redacted] to about [redacted]. As President of the Forest Research Institute, I oversaw the research and development team of up to approximately [redacted], including roughly [redacted] Forest employees and another [redacted] consultants or other staff.

7. R&D is a significant risk for a branded pharmaceutical company. Developing a new drug takes years of trial and error, even when successful. During development, products must pass years of rigorous testing required under the U.S. Food and Drug Administration's process for approving a new drug (the New Drug Application process, or NDA). It may take many years to conduct an R&D program that satisfies the testing required to have an NDA approved by the FDA for a compound. The clinical component alone can take five or more years. The FDA itself often takes approximately one year, if not longer, to approve an NDA.

8. Forest could invest years of time and hundreds of millions of dollars into developing a drug, or searching for additional indications for one of its existing drugs, only to have that drug fail a testing protocol or otherwise fail to be a commercially viable drug product.

9. A key aspect of Forest's business strategy was to partner with other companies to develop new products. In the case of the Alzheimer's treatment NAMENDA®, Forest partnered with Merz Pharmaceuticals, a German company. In approximately 2000, Forest licensed certain IP from Merz and worked to gain approval for the NAMENDA® (IR) tablet for sale in the United States. The active ingredient in NAMENDA® and NAMENDA XR® is a chemical compound called memantine hydrochloride ("memantine").

Development and Use of NAMENDA XR®

10. When I arrived at Forest in 2007, Forest was already manufacturing and selling twice-daily NAMENDA® tablets and oral solution. Many of the other Alzheimer's drugs, Pfizer's Aricept® in particular, were once-daily therapies. Forest was working on the development of its own once-daily Alzheimer's therapy, NAMENDA XR®. Unlike NAMENDA®, NAMENDA XR® is a capsule product that offers extended release of memantine and is approved for a once-a-day administration.

11. Forest spent a significant number of years and devoted substantial resources in developing an innovative formulation for NAMENDA XR® and in conducting the clinical testing. Forest tested NAMENDA XR® in combination with not only Aricept®, the leading acetylcholinesterase inhibitor, but also in combination with the other commercially available acetylcholinesterase inhibitors, Exelon® and Razadyne®. Acetylcholinesterase inhibitors are prescribed for the symptomatic treatment of Alzheimer's disease – including the moderate to severe forms of Alzheimer's disease for which NAMENDA® and NAMENDA XR® are indicated.

12. In many cases, physicians prescribe Aricept®, Exelon® and Razadyne® (or their generic equivalents) instead of NAMENDA® or NAMENDA XR®. In other cases, as described below, physicians prescribe an acetylcholinesterase inhibitor like Aricept® together with NAMENDA® or NAMENDA XR®. Forest launched NAMENDA XR® in June 2013, and has since that time sold both the oral solution and tablet forms of NAMENDA® as well as NAMENDA XR®.

Benefits of NAMENDA XR®

13. NAMENDA XR® offers significant benefits over NAMENDA® (IR) tablets and oral solution. Three of those benefits are briefly discussed below.

14. **Once-Daily Dosing of NAMENDA XR®.** As a physician, I believe that having a once-daily NAMENDA XR® therapeutic regimen can make a significant difference in ensuring compliance – *i.e.*, that the patient actually takes his or her medicine and takes that medicine in the appropriate doses. The benefit of once-daily dosing is supported by a vast body of evidence in the scientific literature. Increased compliance was one of the major things that Forest wanted to accomplish with NAMENDA XR®.

15. **Applesauce Dosing of NAMENDA XR®.** A second benefit of NAMENDA XR® capsules is that they offer dosing advantages over NAMENDA® tablets, including that they are easier to administer in certain clinical circumstances. For example, the patient or the caregiver can open the NAMENDA XR® capsules and sprinkle their contents over applesauce (applesauce is used in the testing for this clinical benefit). Because Forest tested NAMENDA XR® for this dosing benefit and was approved by the FDA, this benefit is specifically listed on NAMENDA XR®'s FDA-approved label. In contrast, NAMENDA® tablets were not approved by the FDA for applesauce dosing, and therefore Forest may not promote NAMENDA® tablets as having the applesauce dosing benefit.

16. NAMENDA XR® offers the benefit of once-daily dosing and applesauce dosing, while maintaining a similar safety profile to NAMENDA®. NAMENDA XR® is surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of NAMENDA XR® can be administered once-daily without a concomitant increase in side effects.

17. **NAMENDA XR® Is a Bridge to the Innovative NAMENDA® Fixed Dose Combination.** A third benefit of NAMENDA XR® is that it allows Forest to make progress towards an additional NAMENDA® innovation presently pending FDA approval — a NAMENDA® combination formulation that also contains donepezil hydrochloride ("donepezil"). Donepezil (Aricept®) is the most widely prescribed medication for the treatment of Alzheimer's disease. Although many patients receive donepezil or NAMENDA® alone, for many other patients the prescribing physician may decide to administer NAMENDA® in combination with donepezil.

18. NAMENDA® (IR) tablets are a twice-daily medication. This means that some Alzheimer's patients that are taking both NAMENDA® tablets and donepezil are taking Alzheimer's medications twice-a-day, for a total of three pills — two NAMENDA® (IR) tablets and one donepezil capsule. This could add significant burden to the patient and the patient's caregiver, particularly in light of the significant possibility that the patient must take numerous other pills for other health issues.

19. To this end, Forest is developing a once-a-day fixed-dose combination of donepezil and NAMENDA XR®. A necessary step to producing this fixed-dose combination was the development of NAMENDA XR®, a once-a-day memantine formulation. The fixed-dose combination would reduce the Alzheimer's medication burden from originally three pills (with a twice-a-day dosing regimen) down to one pill (with a once-a-day dosing regimen). This will provide a significant benefit to patients and their caregivers. Again, a reduction in pill burden can help increase compliance, as well as reduce medication administration errors. The more pills a patient has to take, the greater chance for medical administration errors by the caregiver or staff. And, even more broadly, it reduces the burden on the patient and the caregiver. Moreover, the administration of a fixed dose combination ensures a more predictable pharmacological distribution and disposition of the two drugs.

20. Obtaining FDA approval for the once-daily NAMENDA XR® capsules was an important step in creating a path for approval to the NAMENDA® fixed-dose combination.

<u>Clinical Studies Confirm Ease of Switching and Efficacy</u>

21. With regard to the clinical development for NAMENDA XR®, Forest conducted an extensive program that included four clinical studies in order to establish the safety, tolerability, and efficacy of NAMENDA XR®. These studies include, among other things: (1) an evaluation of the safety and tolerability of NAMENDA XR®, including an evaluation of the switching of patients from twice-a-day NAMENDA® (IR) tablets to once-a-day NAMENDA XR® without titration (MD-51); (2) an evaluation of the safety and efficacy of NAMENDA XR® when administered in combination with each of the popular acetylcholinesterase inhibitors donepezil,

rivastigmine and galantamine (brand names Aricept®, Exelon® and Razadyne®, respectively) (MD-50); and (3) two extension studies, further evaluating the long-term safety and tolerability of NAMENDA XR® (MD-54, MD-82). Attached as Exhibit A (MD-50), Exhibit B (MD-51), Exhibit C (MD-54), and Exhibit D (MD-82) are true and correct copies of the Study Information for each of the four clinical studies. These summaries are publicly available on Forest's website.

22. These clinical studies showed the long term safety and tolerability of NAMENDA XR®, as well as the ability for patients to safely switch from NAMENDA® to NAMENDA XR® without titration. The clinical trial results have been presented and discussed at several academic Alzheimer's conferences to educate physicians and to further potential additional study in this area. Attached as (Exs. E-H) true and correct copies of posters, presenting the results of these studies at recent conferences.

Patients Can Switch From NAMENDA XR® Back To NAMENDA® Tablets If Needed

23. Concerns about whether patients can switch from NAMENDA XR® capsules to NAMENDA® IR tablets are misguided. As the labeling for NAMENDA XR® indicates, and as we informed caregivers and physicians, patients may switch from NAMENDA® (IR) to NAMENDA XR® the next day without titration. The ability to switch without titration was the focus of one arm of the MD-51 clinical trial (Exhibit B).

24. I am not aware of any reason why patients could not switch back from NAMENDA XR® to NAMENDA® (IR) the next day if desired. While Forest believes that NAMENDA XR® is a better product, if a patient desires to return to the twice-daily NAMENDA® (IR) tablet regimen, the patient should be able to do so with no impact on their treatment. The active ingredient is the same in both: memantine. Based on my medical experience and work and research specifically with NAMENDA® and NAMENDA XR®, I am not aware of a medical reason why the switch would lead to adverse effects.

NAMENDA XR® Pediatric Autism Studies Were Costly but Advanced Science

25. By 2009, Forest began evaluating whether memantine could be approved for the treatment of pediatric autism. Forest conducted a series of clinical studies for this indication at a total cost of nearly [redacted].

26. The FDA specifically requested that Forest conduct these studies. As a reward, pursuant to a statute designed to encourage pharmaceutical companies to study certain drugs in children, FDA granted Forest an additional six months of market exclusivity for NAMENDA® (IR) and NAMENDA XR®.

27. Unfortunately, the Phase II clinical trial for NAMENDA® for pediatric autism treatment did not meet its primary endpoints. However, six of the children achieved promising results with NAMENDA®. Forest has discussed the autism clinical trial results at several academic conferences to educate physicians and to further potential additional study in this area. Attached is a true and correct copy of one of Forest's posters summarizing the autism clinical

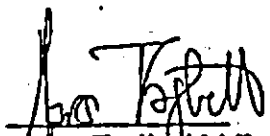
trials as Exhibit I. In science, even failures help us to make advancements towards potential new therapies.

28. Moreover, by designing, funding and running these clinical studies for pediatric autism, Forest developed for the first time a network of over 185 clinical study sites for autism that had never existed before. This network is now available for testing the next new potential treatment for pediatric autism.

Oral Solution Can Be Taken By NAMENDA® Patients

29. While NAMENDA® (IR) patients would benefit from switching to NAMENDA XR®, as stated above, Forest also makes and sells the twice-daily oral solution version of NAMENDA® (IR) that has memantine as its active ingredient. Forest has confirmed in its press releases of February 14, 2014 and June 10, 2014 that it plans to continue selling the twice-daily NAMENDA® (IR) oral solution. Therefore, there is no reason why a NAMENDA® (IR) patient could not take the oral solution if the patient desires to remain on the twice-daily NAMENDA® (IR) dosing regimen. Moreover, unlike the NAMENDA® (IR) tablet, the NAMENDA® oral solution provides an advantage for patients who have difficulty swallowing pills.

I hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that this declaration was executed in Jersey City, New Jersey on October 20, 2014.



Marco Taglietti M.D.

EXHIBIT A

(Filed Under Seal)

Study Information

Study No.	MEM-MD-50
Title	A Randomized, Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of Memantine in Patients with Moderate-to-Severe Dementia of the Alzheimer's Type
Rationale	The study was designed to provide a systematic evaluation of the safety and efficacy of a once-a-day extended-release formulation of memantine in the treatment of outpatients diagnosed with moderate to severe dementia of the Alzheimer's type receiving concurrent stable acetylcholinesterase inhibitor (AChEI) therapy.
Phase	III
Study Period	
First Patient First Visit	June 16, 2005
Last Patient Last Visit	October 4, 2007
Study Design	Multicenter, randomized, double-blind, placebo-controlled, parallel-group, 24-week study
Centers	83 centers in 4 countries: 23 in Argentina, 11 in Chile, 11 in Mexico, and 38 in the United States
Indication	Moderate to severe dementia of the Alzheimer's type
Treatment	Memantine 28 mg/d or placebo, administered orally
Objectives	To evaluate the safety, tolerability, and efficacy of memantine compared to placebo in outpatients diagnosed with moderate-to-severe Alzheimer's disease receiving a concurrent AChEI
Primary Efficacy Variables	Severe Impairment Battery (SIB) Clinician's Interview-Based Impression of Change–Plus version (CIBIC-Plus)
Secondary Efficacy Variable	Alzheimer's Disease Cooperative Study–Activities of Daily Living Inventory ($ADCS\text{-}ADL_{19}$)
Statistical Methods	The primary efficacy parameters were the change from baseline in the SIB total score and the CIBIC-Plus rating at Week 24, using the last observation carried forward (LOCF) approach. Change from baseline in SIB total score was analyzed using a two-way analysis of covariance (ANCOVA) model with treatment group and center as the factors and baseline as a covariate. CIBIC-plus rating was analyzed using the Cochran-Mantel-Haenszel test, controlling for study center.
Study Population	Male or female outpatients ≥ 50 years of age who have: a diagnosis of probable Alzheimer's disease according to criteria of NINCDS-ADRDA (National Institute of Neurological and Communicative Disorders and Stroke - Alzheimer's Disease and Related Disorders Association) and DSM-IV-TR (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision); Mini Mental State Examination scores between 3 and 14, inclusive, at Screening and Baseline; and confirmatory magnetic resonance imaging or computed tomography within the past 12 months. Eligible patients must have been receiving ongoing AChEI therapy at a stable dose for at least 3 months before Screening, and should remain on the same dose throughout the study.

Patient Disposition and Demographics

	Placebo/AChEI	*Memantine extended-release/AChEI*
Number of Subjects		
Planned, n	300	300
Randomized, n	335	342
Safety Population, n	335	341
ITT Population, n	328	333
Completed, n (%)[a]	272 (81.2)	273 (79.8)
Total number of subjects withdrawn, n (%)[a]	63 (18.8)	69 (20.2)
Withdrawn due to adverse events, n (%)[a]	21 (6.3)	34 (9.9)
Withdrawn due to lack of efficacy, n (%)[a]	8 (2.4)	3 (0.9)
Withdrawn for other reasons, n (%)[a]	34 (10.1)	32 (9.4)
Demographics[b]		
Females, n (%)[b]	243 (72.5)	244 (71.6)
Age, years, mean ± SD[b]	76.8 ± 7.76	76.2 ± 8.35
Caucasian, n (%)[b]	312 (93.1)	324 (95.0)
Black, n (%)[b]	12 (3.6)	3 (0.9)
Asian, n (%)[b]	0	1 (0.3)
Other, n (%)[b]	11 (3.3)	13 (3.8)

a Percentages are relative to the Randomized Population.
b Percentages are relative to the Safety Population.
AChEI = acetylcholinesterase inhibitor; ITT = Intent to treat.

Efficacy Results

	Placebo/AChEI	*Memantine extended-release/AChEI*
Primary Efficacy Variables		
SIB		
n	327	332
Baseline, mean ± SEM	75.2 ± 1.07	76.8 ± 0.96
Change from Baseline at Week 24 (LOCF), mean ± SEM	0.3 ± 0.63	2.7 ± 0.61
LSMD	2.6	
95% CI	1.0, 4.2	
p-value	0.001	
CIBIC-Plus		
n	328	333
Score at Week 24 (LOCF), mean ± SEM	4.1 ± 0.07	3.8 ± 0.07
p-value	0.008	
Secondary Efficacy Variable		
ADCS-ADL$_{19}$		
n	328	331
Baseline, mean ± SEM	32.8 ± 0.61	33.1 ± 0.61
Change from Baseline at Week 24 (LOCF), mean ± SEM	−1.3 ± 0.42	−0.7 ± 0.38
LSMD	0.7	

AChEI = acetylcholinesterase inhibitor; ADCS-ADL$_{19}$ = Alzheimer's Disease Cooperative Study–Activities of Daily Living Inventory; CIBIC-Plus = Clinician's Interview-Based Impression of Change-Plus version; LOCF = last observation carried forward; LSMD = least squares mean difference (memantine-placebo); SIB = Severe Impairment Battery.

Safety Results

An adverse event that occurred during the double-blind treatment period was defined as a *treatment-emergent adverse event* (TEAE) if the AE was either not present at or before the day of the first dose of double-blind study medication or was present at or before the day of the first dose of double-blind study medication and increased in severity during the double-blind treatment period. An *on-therapy serious adverse event* (SAE) was defined as an SAE with onset on or after the start date of double-blind study medication and up to 30 days after the last dose of double-blind medication.

Most Frequent Treatment-Emergent Adverse Events

	Placebo/AChEI	*Memantine extended-release/AChEI*
Safety Population, N	335	341
Subjects with at least one TEAE, n (%)	214 (63.9)	214 (62.8)
Fall	26 (7.8)	19 (5.6)
Urinary tract infection	24 (7.2)	19 (5.6)
Headache	17 (5.1)	19 (5.6)
Diarrhea	13 (3.9)	17 (5.0)
Insomnia	16 (4.8)	14 (4.1)
Dizziness	5 (1.5)	16 (4.7)
Agitation	15 (4.5)	14 (4.1)
Influenza	9 (2.7)	15 (4.4)
Hypertension	8 (2.4)	13 (3.8)
Anxiety	9 (2.7)	12 (3.5)
Weight decreased	11 (3.3)	5 (1.5)
Edema peripheral	11 (3.3)	3 (0.9)
Nasopharyngitis	10 (3.0)	6 (1.8)

AChEI = acetylcholinesterase inhibitor; TEAE = treatment-emergent adverse event.

Serious Adverse Events—On-Therapy

Fatal SAEs occurred in four memantine-treated patients and five placebo-treated patients. No fatal SAEs were considered by the Investigator to be related to memantine treatment; one fatal SAE was considered by the Investigator to be related to placebo treatment.

Nonfatal SAEs were reported in 42/676 (6.2%) patients, of which 11 SAEs were considered by the Investigator to be related to study medication.

Serious Adverse Events

	Placebo/AChEI	*Memantine extended-release/AChEI*
Safety Population, N	335	341
Subjects with nonfatal SAEs, n (%) [n related]	18 (5.4) [5]	24 (7.0) [4]
Fall	5 (1.5) [2]	2 (0.6) [0]
Prostate cancer (males only)*	1 (1.1) [0]	0
Urinary tract infection	3 (0.9) [0]	2 (0.6) [0]
Cardiac failure congestive	3 (0.9) [2]	0
Hip fracture	3 (0.9) [2]	0
Pneumonia	0	2 (0.6) [0]
Syncope	0	2 (0.6) [1]
Bradycardia	1 (0.3) [0]	1 (0.3) [1]
Cerebral hemorrhage	1 (0.3) [0]	1 (0.3) [0]
Hypotension	1 (0.3) [0]	1 (0.3) [0]
Ischemic stroke	1 (0.3) [0]	1 (0.3) [0]
Anorexia	0	1 (0.3) [0]
Anticoagulation drug level above therapeutic	0	1 (0.3) [0]
Anxiety disorder due to a general medical condition	0	1 (0.3) [0]
Atrioventricular block complete	0	1 (0.3) [0]
Back pain	0	1 (0.3) [0]
Bacteremia	1 (0.3) [0]	0
Cardio-respiratory arrest	1 (0.3) [0]	0
Cerebrovascular accident	0	1 (0.3) [0]
Chest pain	0	1 (0.3) [0]
Cholesteatoma	0	1 (0.3) [0]
Convulsion	1 (0.3) [1]	0
Deep vein thrombosis	0	1 (0.3) [0]
Delusion	0	1 (0.3) [0]
Diarrhea	0	1 (0.3) [0]
Excessive skin	0	1 (0.3) [0]
Facial paresis	0	1 (0.3) [0]

	Placebo/AChEI	*Memantine extended-release/AChEI*
Head injury	1 (0.3) [0]	0
Herpes zoster	1 (0.3) [0]	0
Hypoglycemia	1 (0.3) [0]	0
Hypokalemia	1 (0.3) [0]	0
Lobar pneumonia	0	1 (0.3) [0]
Meningitis bacterial	0	1 (0.3) [0]
Myoclonus	0	1 (0.3) [0]
Pneumothorax traumatic	0	1 (0.3) [0]
Proctocolectomy	0	1 (0.3) [0]
Rectal prolapse	0	1 (0.3) [0]
Renal failure	0	1 (0.3) [0]
Renal neoplasm	0	1 (0.3) [0]
Sinus bradycardia	0	1 (0.3) [0]
Skin laceration	0	1 (0.3) [0]
Spinal compression fracture	0	1 (0.3) [0]
Syncope vasovagal	0	1 (0.3) [1]
Toothache	0	1 (0.3) [0]
Transient ischemic attack	0	1 (0.3) [1]
Traumatic brain injury	1 (0.3) [0]	0
Urinary retention	1 (0.3) [0]	0
Vomiting	0	1 (0.3) [0]
*Males: placebo N = 92, memantine N = 97.		
Subjects with fatal SAEs, n (%) [n related]	5 (1.5) [1]	4 (1.2) [0]
Pneumonia aspiration	1 (0.3) [0]	1 (0.3) [0]
Cardiac arrest	1 (0.3) [0]	0
Cardio-respiratory arrest	1 (0.3) [1]	0
Cerebrovascular accident	0	1 (0.3) [0]
Dementia Alzheimer's type	0	1 (0.3) [0]
Drowning	1 (0.3) [0]	0
General physical health deterioration	0	1 (0.3) [0]
Intracranial hematoma	1 (0.3) [0]	0
Metastatic carcinoma of the bladder	0	1 (0.3) [0]
Myocardial infarction	1 (0.3) [0]	0
Respiratory arrest	1 (0.3) [0]	0

AChEI = acetylcholinesterase inhibitor; SAE = serious adverse event.

Conclusions
The change from Baseline to Week 24 in SIB total score and the CIBIC-Plus rating at Week 24 in memantine-treated patients were significantly different from those in placebo-treated patients in favor of memantine (SIB: $p = 0.001$; CIBIC-Plus: $p = 0.008$) using the LOCF approach. The pertinent safety findings are noted above.

Publications
None

EXHIBIT B

(Filed Under Seal)

Study Information

Study No.	MEM-MD-51	
Title	An Open-label Evaluation of the Safety of Memantine in Patients With Moderate-to-Severe Dementia of the Alzheimer's Type	
Rationale	The study was designed to evaluate the long-term safety and tolerability of a once-a-day extended-release (ER) formulation of memantine in the treatment of outpatients with a diagnosis of moderate to severe dementia of the Alzheimer's type	
Phase	III	
Study Period		
First Patient First Visit	July 22, 2005	
Last Patient Last Visit	March 4, 2008	
Study Design	Multicenter, open-label, 52-week study. Patients not taking memantine at study entry were treated with memantine ER starting with a 4-week titration followed by treatment at the target dose. Patients taking memantine 10 mg BID at study entry switched to the memantine ER treatment with no titration.	
Centers	31 US centers	
Indication	Moderate to severe dementia of the Alzheimer's type	
Treatment	Memantine ER 28 mg/d, administered orally	
	Group 1 *(Not taking memantine at study entry)*	*Group 2* *(Taking memantine 10 mg BID at study entry)*
	7-mg memantine ER capsules *4-step titration* *Start: 7 mg/d* *Weekly increase by 7 mg/d* *Final dose: 28 mg once daily*	*Immediate switch to 28-mg memantine ER capsule* *No titration* *Final dose: 28 mg once daily*
Objectives	To evaluate the safety and tolerability of memantine in outpatients diagnosed with moderate-to-severe dementia of the Alzheimer's type	
Statistical Methods	Safety analyses were based on the Safety Population, defined as all enrolled patients who received at least one dose of open-label study drug.	
Study Population	Male or female patients 50 years of age or older with diagnostic evidence of probable Alzheimer's disease consistent with NINCDS-ADRDA (National Institute of Neurological and Communicative Disorders and Stroke–Alzheimer's Disease and Related Disorders Association) and DSM-IV-TR (*Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, Text Revision) criteria, a Mini Mental State Examination score of at least 3 and not greater than 18 at Screening, and confirmatory magnetic resonance imaging or computed tomography within the past 24 months.	
	Additional Criterion For Patients in Group 1	*Additional Criterion For Patients in Group 2*
	Patient did not take memantine for 30 days or more before Screening.	Patient took memantine 10 mg BID for 30 days or more before Screening.

	Group 1 (Memantine extended-release, 4-step titration)	*Group 2 (Memantine extended-release, immediate switch)*
Number of subjects		
Enrolled, n[a]	130	36
Safety Population, n	128	36
Completed, n (%)	75 (58.6)	23 (63.9)
Total number of subjects withdrawn, n (%)	53 (41.4)	13 (36.1)
Withdrawn because of adverse events, n (%)	32 (25.0)	7 (19.4)
Withdrawn for other reasons, n (%)	21 (16.4)	6 (16.7)
Demographics		
Females, n (%)	82 (64.1)	20 (55.6)
Age (years), mean ± SD	78.0 ± 8.48	75.5 ± 8.97
Caucasian, n (%)	115 (89.8)	35 (97.2)
Black, n (%)	13 (10.2)	1 (2.8)
Asian, n (%)	0	0
Other, n (%)	0	0

a The planned total number of subjects was 150.

Safety Results

An adverse event that occurred during the open-label treatment period was defined as a *treatment-emergent adverse event* if the adverse event was either not present at or before the day of the first dose of open-label study drug or was present at or before the day of the first dose of open-label study drug and increased in severity during the open-label treatment period. An *on-therapy serious adverse event* (SAE) was defined as an SAE with onset on or after the start date of open-label study drug and up to 30 days after the last dose of open-label drug.

Most Frequent Treatment-Emergent Adverse Events

	Group 1 (Memantine extended-release, 4-step titration)	*Group 2 (Memantine extended-release, Immediate switch)*
Safety Population, N	128	36
Subjects with at least one TEAE, n (%)	117 (91.4)	33 (91.7)
Fall	13 (10.2)	6 (16.7)
Urinary tract infection	12 (9.4)	5 (13.9)
Weight increased	8 (6.3)	4 (11.1)
Anxiety	7 (5.5)	4 (11.1)
Constipation	7 (5.5)	4 (11.1)
Weight decreased	13 (10.2)	2 (5.6)
Dizziness	12 (9.4)	0
Somnolence	6 (4.7)	3 (8.3)
Urinary incontinence	4 (3.1)	3 (8.3)
Nasopharyngitis	3 (2.3)	3 (8.3)
Agitation	10 (7.8)	1 (2.8)
Confusional state	10 (7.8)	1 (2.8)
Depression	9 (7.0)	0
Hypertension	8 (6.3)	1 (2.8)
Nausea	8 (6.3)	1 (2.8)
Diarrhea	7 (5.5)	2 (5.6)
Back pain	4 (3.1)	2 (5.6)
Tremor	4 (3.1)	2 (5.6)
Anemia	3 (2.3)	2 (5.6)
Dehydration	2 (1.6)	2 (5.6)
Excoriation	2 (1.6)	2 (5.6)
Hyperhidrosis	2 (1.6)	2 (5.6)
Myocardial infarction	2 (1.6)	2 (5.6)
Basal cell carcinoma	0	2 (5.6)
Hip fracture	0	2 (5.6)
Onychomycosis	0	2 (5.6)

TEAE = treatment-emergent adverse event.

Serious Adverse Events—On-Therapy
Fatal SAEs occurred in 9 patients in Group 1 and 3 patients in Group 2. Three fatal SAEs in Group 1 were considered by the Investigator to be related to memantine treatment. No fatal SAEs in Group 2 were considered by the Investigator to be related to memantine treatment.

Nonfatal SAEs were reported in 38/164 (23.2%) patients; six of these SAEs were considered by the Investigator to be related to study drug.

Serious Adverse Events

	Group 1 (Memantine extended-release, 4-step titration)	*Group 2 (Memantine extended-release, immediate switch)*
Safety Population, N	128	36
Subjects with nonfatal SAEs, n (%) [n related]	30 (23.4) [4]	8 (22.2) [0]
Fall	5 (3.9) [2]	2 (5.6) [0]
Hip fracture	0	2 (5.6) [0]
Syncope	3 (2.3) [1]	1 (2.8) [0]
Myocardial infarction	1 (0.8) [0]	1 (2.8) [0]
Asthenia	0	1 (2.8) [0]
Cellulitis	0	1 (2.8) [0]
Cholelithiasis	0	1 (2.8) [0]
Coronary artery disease	0	1 (2.8) [0]
Hyperhidrosis	0	1 (2.8) [0]
Pubic rami fracture	0	1 (2.8) [0]
Tremor	0	1 (2.8) [0]
Ulna fracture	0	1 (2.8) [0]
Ventricular fibrillation	0	1 (2.8) [0]
Pneumonia	3 (2.3) [0]	0
Aggression	2 (1.6) [1]	0
Agitation	2 (1.6) [1]	0
Femoral neck fracture	2 (1.6) [0]	0
Lobar pneumonia	2 (1.6) [1]	0
Acute coronary syndrome	1 (0.8) [0]	0
Arthropathy	1 (0.8) [0]	0
Atrial fibrillation	1 (0.8) [0]	0
Confusional state	1 (0.8) [0]	0
Dementia	1 (0.8) [0]	0
Drug withdrawal syndrome	1 (0.8) [0]	0
Facial bones fracture	1 (0.8) [0]	0
Fluid retention	1 (0.8) [0]	0
Hypoglycemia	1 (0.8) [0]	0
Joint dislocation	1 (0.8) [0]	0

	Group 1 (Memantine extended-release, 4-step titration)	*Group 2 (Memantine extended-release, immediate switch)*
Large intestine perforation	1 (0.8) [0]	0
Loss of consciousness	1 (0.8) [0]	0
Osteoarthritis	1 (0.8) [0]	0
Pancreatitis acute	1 (0.8) [0]	0
Peritonitis	1 (0.8) [0]	0
Pneumonia aspiration	1 (0.8) [0]	0
Pneumonia bacterial	1 (0.8) [0]	0
Presyncope	1 (0.8) [0]	0
Restlessness	1 (0.8) [0]	0
Rhabdomyolysis	1 (0.8) [0]	0
Septic shock	1 (0.8) [0]	0
Sick sinus syndrome	1 (0.8) [0]	0
Subdural hematoma	1 (0.8) [0]	0
Upper gastrointestinal hemorrhage	1 (0.8) [0]	0
Urinary tract infection	1 (0.8) [0]	0
Subjects with fatal SAEs, n (%) [n related]	9 (7.0) [3]	3 (8.3) [0]
Cardiac arrest	0	1 (2.8) [0]
Hypothermia	0	1 (2.8) [0]
Lung adenocarcinoma	0	1 (2.8) [0]
Aortic aneurysm rupture	1 (0.8) [0]	0
Cardiac failure congestive	1 (0.8) [0]	0
Cardio-respiratory arrest	1 (0.8) [1]	0
Cerebrovascular accident	1 (0.8) [1]	0
Dementia	1 (0.8) [0]	0
Gastrointestinal carcinoma	1 (0.8) [0]	0
Lymphoma	1 (0.8) [0]	0
Pulmonary embolism	1 (0.8) [1]	0
Respiratory failure	1 (0.8) [0]	0

SAE = serious adverse event.

Conclusions
The pertinent safety findings are noted above.

Publications
None.

EXHIBIT C

(Filed Under Seal)

Study Information

Study No.	MEM-MD-54
Title	An Open-Label Extension Study Evaluating the Safety and Tolerability of Memantine in Patients With Moderate to Severe Dementia of the Alzheimer's Type
Rationale	The study was designed to evaluate the long-term safety and tolerability of a once-a-day, extended release formulation of memantine in the treatment of outpatients with a diagnosis of moderate to severe dementia of the Alzheimer's type
Phase	III
Study Period	
First Patient First Visit	April 11, 2006
Last Patient Last Visit	April 25, 2008
Study Design	Multicenter, open-label, 28-week extension study for patients who completed the 24-week, lead-in, double-blind, placebo-controlled study MEM-MD-50
Centers	66 centers in 4 countries: 23 in Argentina, 9 in Chile, 8 in Mexico, and 26 in the United States
Indication	Moderate to severe dementia of the Alzheimer's type
Treatment	Memantine extended release 28 mg/d, administered orally
Objective	To evaluate the safety and tolerability of memantine in outpatients diagnosed with moderate to severe dementia of the Alzheimer's type
Statistical Methods	Safety analyses were based on the *Safety Population*, defined as all enrolled patients who received at least one dose of open-label study drug. All safety variables were summarized by descriptive statistics. Study data were analyzed based on treatment assignments during the lead-in study: the placebo/memantine group was previously randomized to the placebo group and the memantine/memantine group was previously randomized to the memantine group during the double-blind, lead-in study MEM-MD-50.
Study Population	Patients with moderate to severe dementia of the Alzheimer's type who had completed 24 weeks of the lead-in Study MEM-MD-50

Patient Disposition and Demographics

	Placebo/Memantine Extended Release	*Memantine Extended Release/ Memantine Extended Release*
Number of Subjects		
Planned, n	200	200
Enrolled, n	246	246
Safety Population, n	245	246
Completed, n (%)	212 (86.5)	211 (85.8)
Total number of subjects withdrawn, n (%)	33 (13.5)	35 (14.2)
Withdrawn due to adverse events, n (%)	20 (8.2)	25 (10.2)
Withdrawn for other reasons, n (%)	13 (5.3)	10 (4.1)
Demographics		
Females, n (%)	177 (72.2)	175 (71.1)
Age, y, mean ± SD	76.6 ± 7.4	75.4 ± 7.9
Caucasian, n (%)	233 (95.1)	240 (97.6)
Black, n (%)	8 (3.3)	3 (1.2)
Asian, n (%)	0	0
Other, n (%)	4 (1.6)	3 (1.2)

Note: Percentages are relative to the Safety Population

Safety Results

An adverse event that occurred during the open-label treatment period was defined as a *treatment-emergent adverse event* (TEAE) if the adverse event was not present before the day of the first dose of double-blind study drug in lead-in Study MEM-MD-50 or was present before the day of the first dose of double-blind study drug but increased in severity during the open-label treatment period of Study MEM-MD-54. An *on-therapy serious adverse event* (SAE) was defined as an SAE with onset on or after the start date of open-label study drug and up to 30 days after the last dose of open-label study drug.

Most Frequent Treatment-Emergent Adverse Events

	Placebo/Memantine Extended Release	*Memantine Extended Release/ Memantine Extended Release*
Safety Population, N	245	246
Subjects with at least 1 TEAE, n (%)	157 (64.1)	143 (58.1)
Urinary tract infection	19 (7.8)	14 (5.7)
Agitation	4 (1.6)	18 (7.3)
Fall	15 (6.1)	17 (6.9)
Dizziness	15 (6.1)	8 (3.3)
Insomnia	14 (5.7)	9 (3.7)
Somnolence	11 (4.5)	7 (2.8)
Diarrhea	10 (4.1)	9 (3.7)
Pneumonia	10 (4.1)	6 (2.4)
Constipation	9 (3.7)	6 (2.4)
Headache	6 (2.4)	9 (3.7)
Influenza	3 (1.2)	9 (3.7)
Weight decreased	8 (3.3)	6 (2.4)
Cough	4 (1.6)	8 (3.3)
Bronchitis	7 (2.9)	7 (2.8)
Hypertension	7 (2.9)	7 (2.8)
Confusional state	7 (2.9)	6 (2.4)
Upper respiratory tract infection	7 (2.9)	2 (0.8)
Hypotension	3 (1.2)	7 (2.8)
Depression	2 (0.8)	7 (2.8)

TEAE = treatment-emergent adverse event.

Serious Adverse Events—On-Therapy

Fatal SAEs occurred in 8 patients in the placebo/memantine extended release group and in 10 patients in the memantine extended release/memantine extended release group. No fatal SAEs in the placebo/memantine extended release group were considered by the Investigator to be related to memantine treatment. One patient in the memantine extended release/memantine extended release group reported three SAEs which were considered by the investigator to be associated with patient's death and related to memantine treatment.

Nonfatal SAEs were reported in 43/491 (8.8%) patients; nine of these SAEs were considered by the Investigator to be related to the study drug.

Serious Adverse Events

	Placebo/Memantine Extended Release	*Memantine Extended Release/ Memantine Extended Release*
Safety Population, N	245	246
Subjects with nonfatal SAEs, n (%) [n related]	17 (6.9) [1]	26 (10.6) [6]
Fall	4 (1.6) [0]	8 (3.3) [1]
Pneumonia	5 (2.0) [0]	3 (1.2) [0]
Dehydration	3 (1.2) [0]	2 (0.8) [0]
Hip fracture	1 (0.4) [0]	3 (1.2) [1]
Femoral neck fracture	0	3 (1.2) [0]
Urinary tract infection	1 (0.4) [0]	2 (0.8) [0]
Renal failure acute	0	2 (0.8) [0]
Cardiac failure congestive	1 (0.4) [0]	1 (0.4) [0]
Femur fracture	1 (0.4) [0]	1 (0.4) [0]
Mental status changes	1 (0.4) [0]	1 (0.4) [0]
Abdominal pain	1 (0.4) [0]	0
Agitation	0	1 (0.4) [1]
Angina pectoris	0	1 (0.4) [0]
Asthenia	1 (0.4) [0]	0
Behavioral and psychiatric symptoms of dementia	0	1 (0.4) [0]
Bronchitis	0	1 (0.4) [1]
Bronchopneumonia	0	1 (0.4) [0]
Cardiac failure	1 (0.4) [0]	0
Colon cancer	0	1 (0.4) [0]
Dementia of the Alzheimer's type, with depressed mood	0	1 (0.4) [0]
Depressed level of consciousness	0	1 (0.4) [0]
Diabetes mellitus inadequate control	1 (0.4) [0]	0
Diarrhea	1 (0.4) [0]	0
Drug withdrawal syndrome	0	1 (0.4) [1]
Gastroenteritis viral	0	1 (0.4) [0]
Head injury	0	1 (0.4) [0]
Hypertensive crisis	0	1 (0.4) [0]
Hypotension	0	1 (0.4) [1]
Inguinal hernia	1 (0.4) [0]	0
Joint dislocation	0	1 (0.4) [0]
Loss of consciousness	0	1 (0.4) [1]

Serious Adverse Events

	Placebo/Memantine Extended Release	*Memantine Extended Release/ Memantine Extended Release*
Lung infection	0	1 (0.4) [0]
Myoclonus	1 (0.4) [1]	0
Pelvic mass	1 (0.4) [0]	0
Sepsis	1 (0.4) [0]	0
Status epilepticus	0	1 (0.4) [1]
Syncope	0	1 (0.4) [0]
Traumatic brain injury	1 (0.4) [0]	0
Upper respiratory tract infection	0	1 (0.4) [0]
Wrist fracture	1 (0.4) [0]	0
Subjects with fatal SAEs, n (%) [n related]	8 (3.3) [0]	10 (4.1) [1]
Pneumonia	3 (1.2) [0]	1 (0.4) [0]
Cardio-respiratory arrest	2 (0.8) [0]	1 (0.4) [0]
Acute myocardial infarction	1 (0.4) [0]	1 (0.4) [1]
Acute respiratory failure	0	1 (0.4) [0]
Aspiration	0	1 (0.4) [0]
Bundle branch block	0	1 (0.4) [1]
Cardiac arrest	1 (0.4) [0]	0
Cardiopulmonary failure	1 (0.4) [0]	0
Colon cancer	0	1 (0.4) [0]
Dehydration	0	1 (0.4) [0]
Dementia Alzheimer's type	1 (0.4) [0]	0
Gastrointestinal hemorrhage	0	1 (0.4) [0]
Hip fracture	0	1 (0.4) [0]
Hypotension	0	1 (0.4) [0]
Infected skin ulcer	1 (0.4) [0]	0
Pulmonary embolism	0	1 (0.4) [0]
Pulmonary sepsis	0	1 (0.4) [0]
Renal failure acute	1 (0.4) [0]	0
Sepsis	0	1 (0.4) [0]
Subarachnoid hemorrhage	0	1 (0.4) [0]
Ventricular arrhythmia	0	1 (0.4) [1]

SAE = serious adverse event.

Conclusions
The pertinent safety findings are noted above.

Publications
None.

EXHIBIT D

(Filed Under Seal)

Study Information

Study No.	MEM-MD-82
Title	An Open-label Extension Study Evaluating the Safety of Memantine in Patients With Moderate to Severe Dementia of the Alzheimer's Type
Rationale	This study was designed to evaluate the long-term safety and tolerability of a once-a-day extended release (ER) formulation of memantine in the treatment of outpatients with a diagnosis of moderate to severe dementia of the Alzheimer's type and who completed one of the lead-in studies, either MEM-MD-51 or MEM-MD-54
Phase	3
Study Period	
First Patient First Visit	11 Jul 2007
Last Patient Last Visit	14 Apr 2009
Study Design	Multicenter, open-label, 52-week extension study for patients who completed the lead-in, open-label, 52-week Study MEM-MD-51 or the 28-week extension Study MEM-MD-54
Centers	24 centers in the United States
Indication	Moderate to severe dementia of the Alzheimer's type
Treatment	Memantine ER 28 mg/day once daily, administered orally
Objectives	To evaluate the long-term safety and tolerability of memantine ER in outpatients who have been diagnosed with moderate to severe dementia of the Alzheimer's type
Primary Efficacy Measure	Not applicable
Secondary Efficacy Measure	Not applicable
Statistical Methods	The safety analyses were performed on the Safety Population, which comprised all enrolled patients who took at least one dose of open-label memantine ER in this study. All safety variables were summarized by descriptive statistics.
Study Population	Patients with moderate to severe dementia of the Alzheimer's type who had completed either 28 weeks of treatment in Study MEM-MD-54 or 52 weeks of treatment in Study MEM-MD-51 at a final dose of memantine ER 28 mg/day, administered orally.

Patient Disposition and Demographics

	Memantine Extended Release
Number of Patients	
Planned, n	175
Enrolled, n	67
Safety Population, n	66
Completed, n (%)	44 (66.7)
Total number of patients withdrawn, n (%)	22 (33.3)
Withdrawn due to adverse events, n (%)	8 (12.1)
Withdrawn for other reasons, n (%)	14 (21.2)
Demographics	
Females, n (%)	39 (59.1)
Age (y), mean ± SD	74.5 ± 8.75
White, n (%)	62 (93.9)
Black, n (%)	4 (6.1)
Asian, n (%)	0
Other, n (%)	0

Note: Percentages are relative to the Safety Population.

Efficacy Results

	Memantine Extended Release
Primary Efficacy Measure	
Not applicable.	
Secondary Efficacy Measure	
Not applicable.	

Safety Results

An adverse event (AE) that occurred during the treatment period in this open-label extension study was defined as a treatment-emergent adverse event (TEAE) if the AE was either not present before the day of the first dose of double-blind study medication in Study MEM-MD-50 (the lead-in study to Study MEM-MD-54) or open-label study medication in Study MEM-MD-51, or was present before the day of the first dose of double-blind study medication in Study MEM-MD-50 or open-label study medication in Study MEM-MD-51 but increased in severity during this open-label extension study. An on-therapy serious adverse event (SAE) was defined as an SAE with onset on or after the start date of open-label study medication in this extension study and up to 30 days after the last dose of open-label study medication.

Most Frequent Treatment-Emergent Adverse Events

	Memantine Extended Release
Safety Population, N	66
Patients with at least one TEAE, n (%)	50 (75.8)
Urinary tract infection	9 (13.6)
Agitation	8 (12.1)
Aggression	7 (10.6)
Dementia Alzheimer's type	6 (9.1)
Anaemia	5 (7.6)
Back pain	5 (7.6)
Constipation	5 (7.6)
Weight decreased	5 (7.6)
Confusional state	4 (6.1)
Fall	4 (6.1)
Upper respiratory tract infection	4 (6.1)

TEAE = treatment-emergent adverse event

Serious Adverse Events—On-Therapy
Two fatal SAEs occurred in 2 patients. The fatal SAEs were considered not related to memantine treatment.

Nonfatal SAEs were reported in 16/66 (24.2%) patients, none of which were considered by the Investigator to be related to study medication.

Serious Adverse Events

	Memantine Extended Release
Safety Population, N	66
Patients with nonfatal SAEs, n (%) [n related]	16 (24.2) [0]
Aggression	2 (3.0) [0]
Dementia Alzheimer's type	2 (3.0) [0]
Pneumonia	2 (3.0) [0]
Respiratory failure	2 (3.0) [0]
Acute myocardial infarction	1 (1.5) [0]
Agitation	1 (1.5) [0]
Anger	1 (1.5) [0]
Anxiety	1 (1.5) [0]
Balance disorder	1 (1.5) [0]
B-cell lymphoma	1 (1.5) [0]
Bronchitis viral	1 (1.5) [0]
Cardiac failure congestive	1 (1.5) [0]
Cholecystitis	1 (1.5) [0]
Confusional state	1 (1.5) [0]
Convulsion	1 (1.5) [0]
Decubitus ulcer	1 (1.5) [0]
Depression	1 (1.5) [0]
Dysarthria	1 (1.5) [0]
Escherichia urinary tract infection	1 (1.5) [0]
Gastric ulcer haemorrhage	1 (1.5) [0]
Gout	1 (1.5) [0]
Mental status changes	1 (1.5) [0]
Metabolic encephalopathy	1 (1.5) [0]
Nausea	1 (1.5) [0]
Thyrotoxic crisis	1 (1.5) [0]
Transient ischaemic attack	1 (1.5) [0]
Vomiting	1 (1.5) [0]
Wound infection bacterial	1 (1.5) [0]
Patients with fatal SAEs, n (%) [n related]	2 (3.0) [0]
Cardiac arrest	1 (1.5) [0]
Dementia Alzheimer's type	1 (1.5) [0]

SAE = serious adverse event

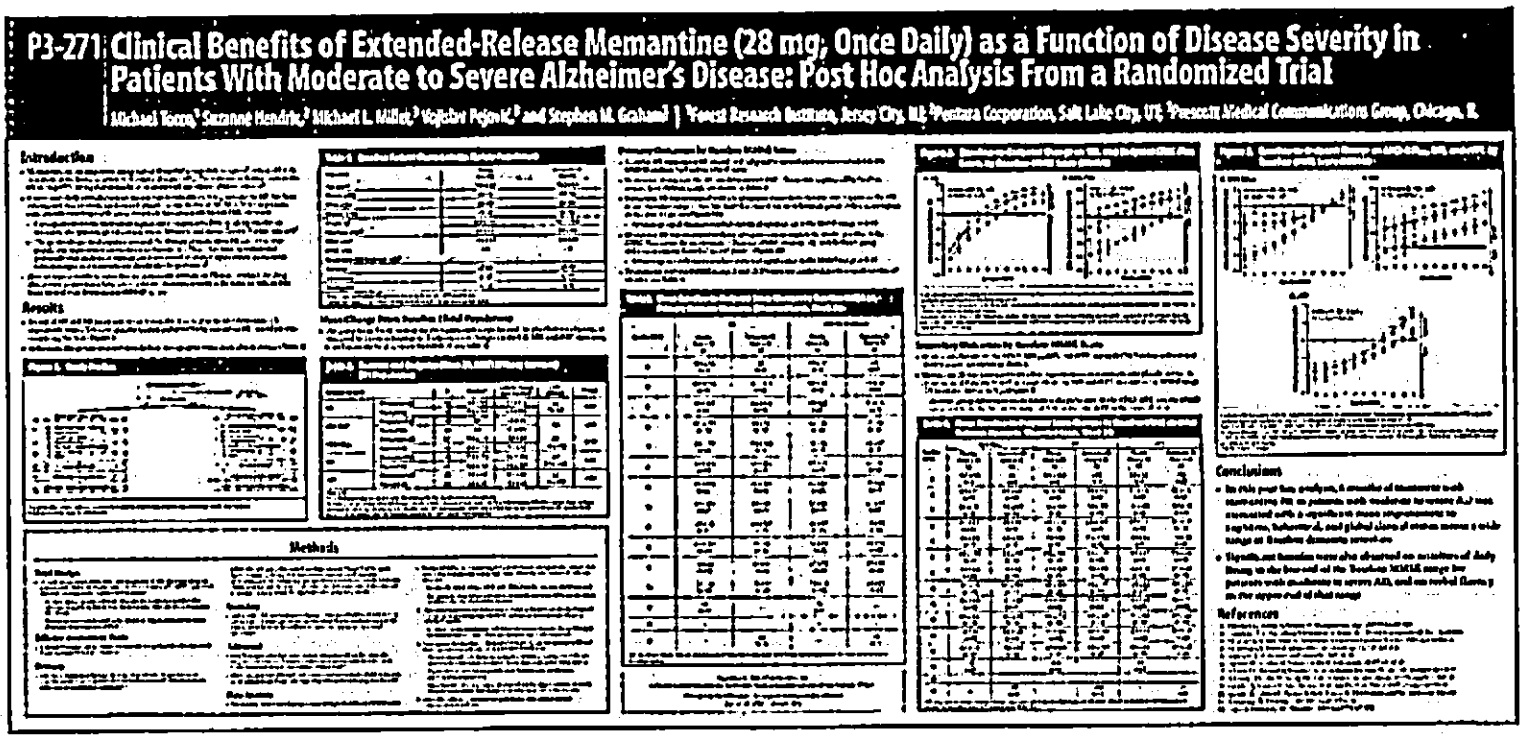
Conclusions
The pertinent safety findings are noted above.

Publications

None.

EXHIBIT E

(Filed Under Seal)



P3-271 Clinical Benefits of Extended-Release Memantine (28 mg, Once Daily) as a Function of Disease Severity in Patients With Moderate to Severe Alzheimer's Disease: Post Hoc Analysis From a Randomized Trial

Introduction

Results

Methods

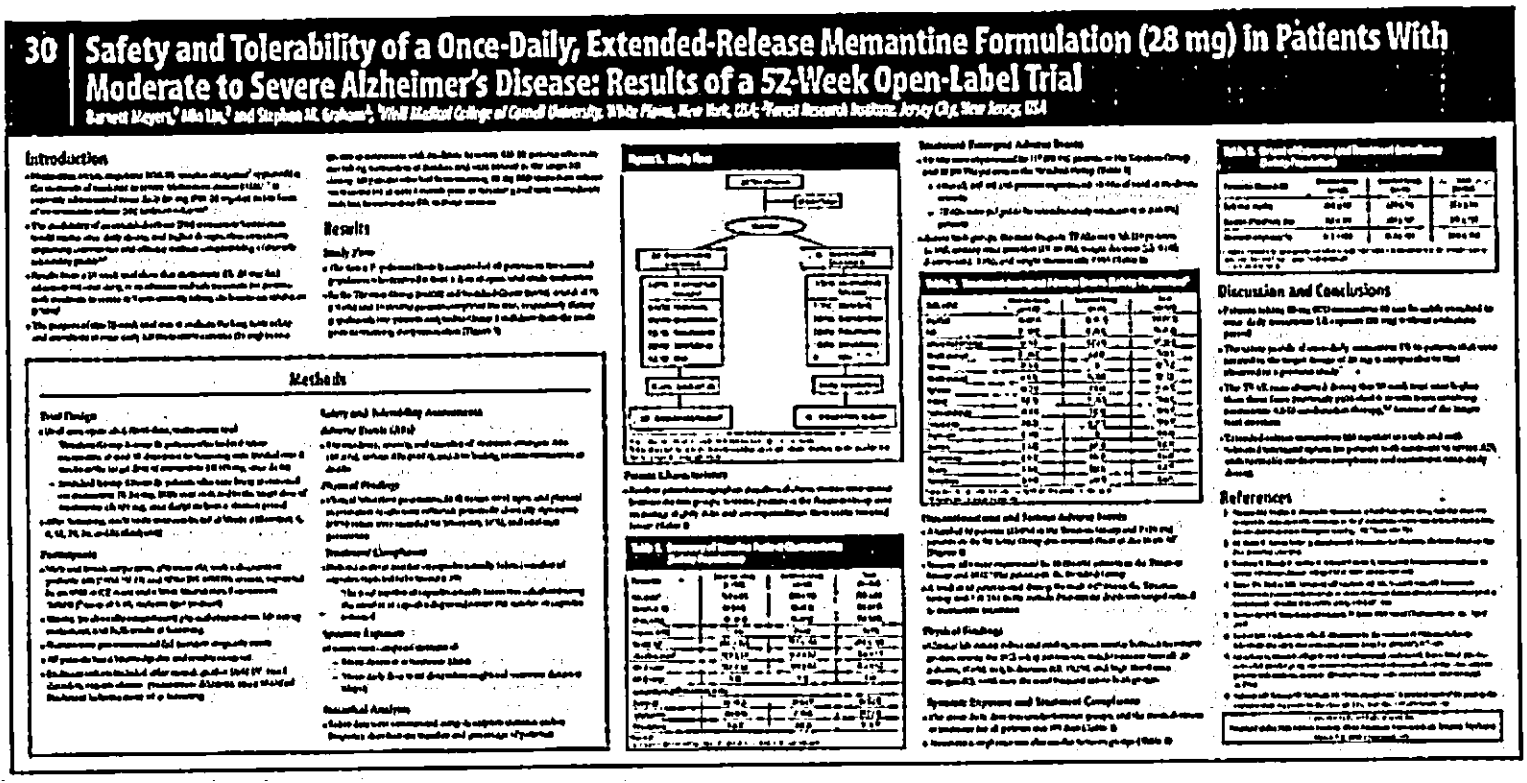
Conclusions

References

HIGHLY CONFIDENTIAL

EXHIBIT F

(Filed Under Seal)



30 | Safety and Tolerability of a Once-Daily, Extended-Release Memantine Formulation (28 mg) in Patients With Moderate to Severe Alzheimer's Disease: Results of a 52-Week Open-Label Trial

Introduction

Methods

Results

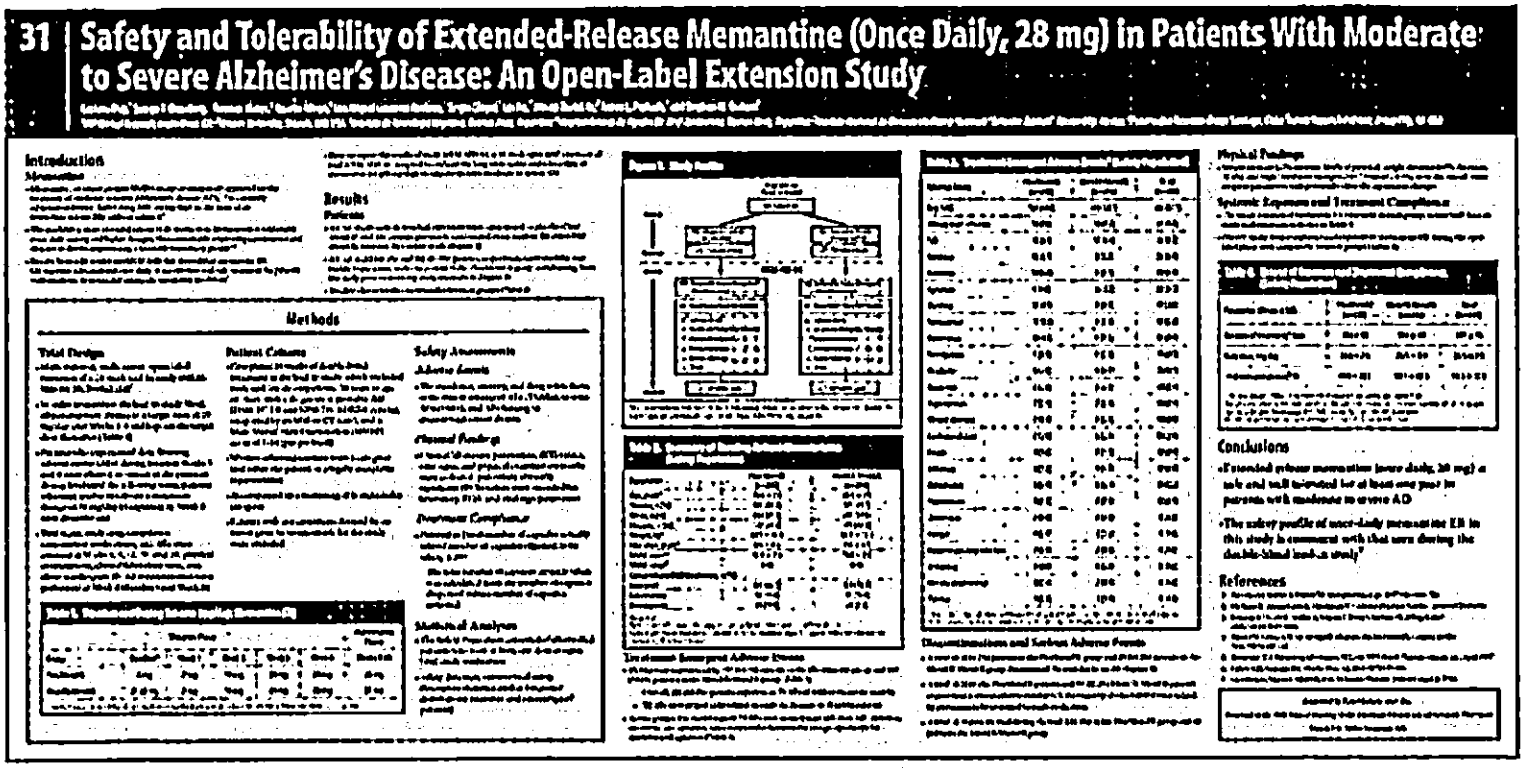
Discussion and Conclusions

References

HIGHLY CONFIDENTIAL

EXHIBIT G

(Filed Under Seal)



31 | Safety and Tolerability of Extended-Release Memantine (Once Daily, 28 mg) in Patients With Moderate to Severe Alzheimer's Disease: An Open-Label Extension Study

Introduction

Methods

Trial Design

Patient Cohorts

Safety Assessments

Adverse Events

Physical Findings

Treatment Compliance

Statistical Analysis

Results

Patients

Physical Findings

Systemic Exposure and Treatment Compliance

Discontinuations and Serious Adverse Events

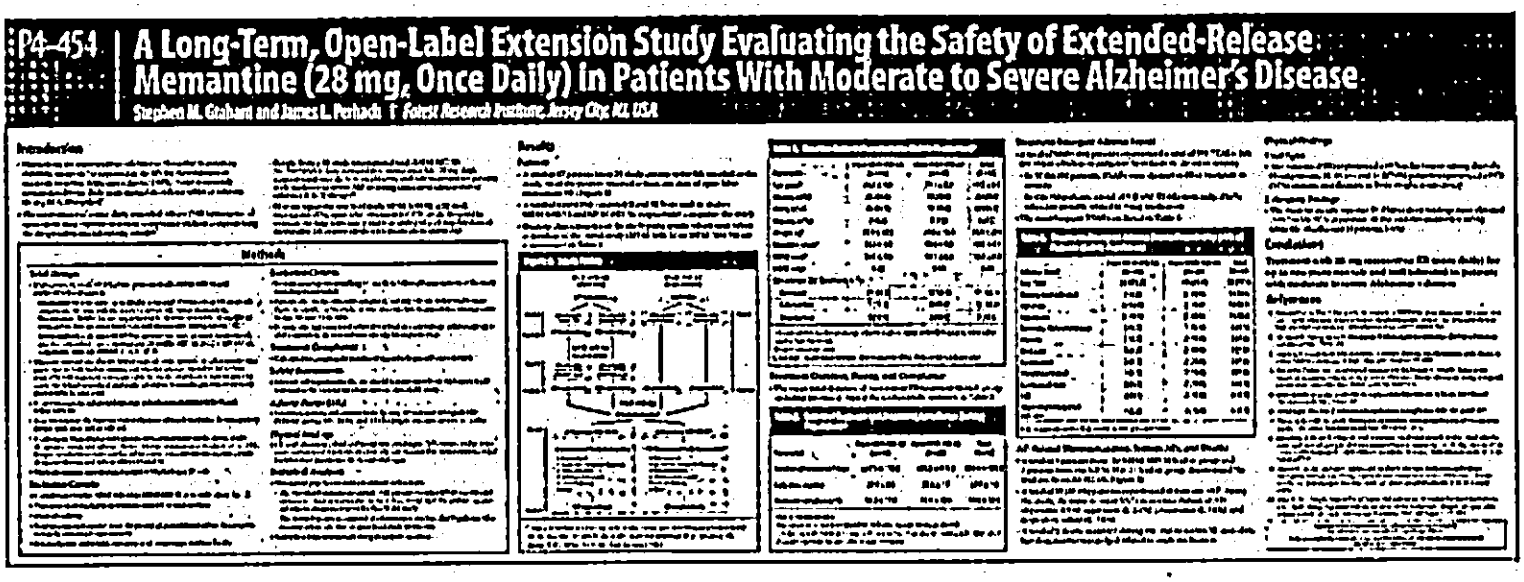
Conclusions

- Extended-release memantine (once daily, 28 mg) is safe and well tolerated for at least one year in patients with moderate to severe AD
- The safety profile of once-daily memantine ER in this study is consistent with that seen during the double-blind treatment study

References

EXHIBIT H

(Filed Under Seal)



P4-454 | A Long-Term, Open-Label Extension Study Evaluating the Safety of Extended-Release Memantine (28 mg, Once Daily) in Patients With Moderate to Severe Alzheimer's Disease

Stephen M. Graham and James L. Perhach † Forest Research Institute, Jersey City, NJ, USA

Introduction

Methods

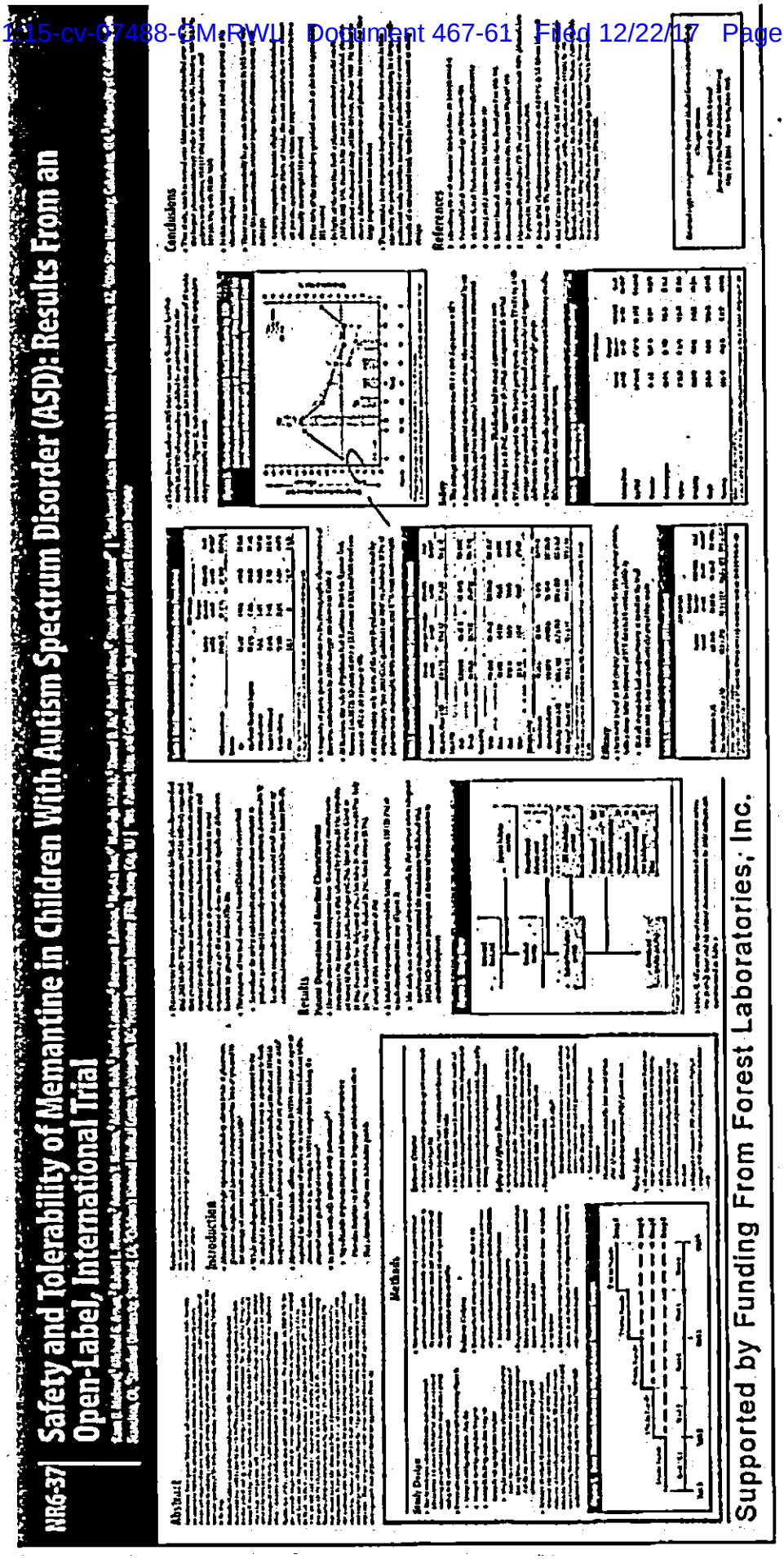
Results

Conclusions

References

EXHIBIT I

(Filed Under Seal)


NR6-37
Safety and Tolerability of Memantine in Children With Autism Spectrum Disorder (ASD): Results From an Open-Label, International Trial
Abstract
Introduction
Methods
Results
Conclusions
References
Supported by Funding From Forest Laboratories, Inc.